

## **SUGAR FREE MENTHOL COUGH DROP- menthol lozenge**

**Supervalu Inc.**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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### **Menthol 5.8 mg**

#### **Active ingredient (in each drop)**

Menthol 5.8 mg

#### **Purpose**

Cough suppressant / Oral anesthetic

Uses temporarily relieves:

cough as may occur with a cold

occasional minor irritation and sore throat

#### **Warnings**

**Sore throat warning:** if sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, swelling, nausea, or vomiting, consult a doctor promptly. If sore mouth symptoms do not improve in 7 days, see your dentist or doctor promptly. These symptoms may be serious.

#### **Ask a doctor before use if you have:**

- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- cough accompanied by excessive phlegm (mucus)

#### **Stop use and ask doctor if**

- cough persists for more than 7 days, tends to recur, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.
- sore throat is severe, or irritation, pain or redness lasts or worsens
- sore mouth does not improve in 7 days.

**If pregnant or breast-feeding,** ask a health professional before use.

**Keep out of reach of children.**

#### **Directions**

adults and children 5 years and over - allow 1 drop to dissolve slowly in mouth. May be repeated every two hours as necessary or as directed by a doctor.

children under 5 years - ask a doctor

#### **Other information**

- 6 calories per drop
- Excess consumption may cause a laxative effect.

**Inactive ingredients:** Acesulfame potassium, corn starch, eucalyptus oil, FD&C blue

#1, FD&C red #40, glycerin, gum arabic, isomalt, maltitol syrup, medium chain triglycerides, natural & artificial flavors, potassium sorbate, soybean oil, sucralose, and water.

**Questions?** Or to report an adverse event call **1-877-932-7948**.



**FEQUALINE®**

sugar free menthol

**cough  
drops**

menthol - cough  
suppressant/  
oral anesthetic

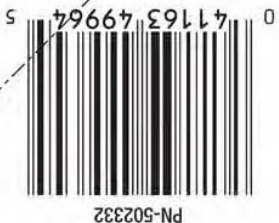
- soothes sore throat pain
- temporarily relieves cough

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EDEN PRAIRIE, MN 55344 USA

MADE IN USA WITH DOMESTIC AND IMPORTED INGREDIENTS  
GLUTEN FREE

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**Drug Facts**

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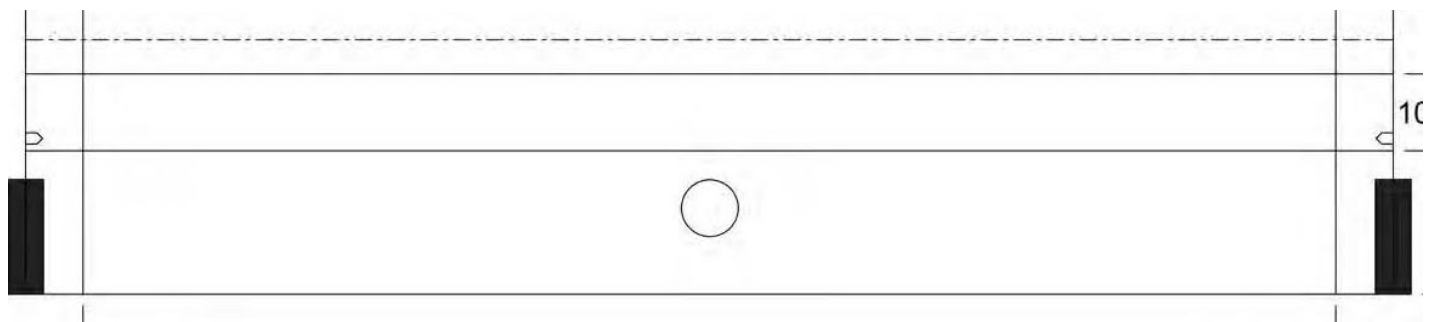
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**Questions?** Or to report an adverse event

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This product is not manufactured or distributed by the owner of the registered trademark HALLS®.



## SUGAR FREE MENTHOL COUGH DROP

menthol lozenge

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41163-034
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5.8 mg

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

### Product Characteristics

Color	blue (Light with Flakes)	Score	score with uneven pieces
Shape	OVAL	Size	16mm
Flavor	MENTHOL	Imprint Code	B
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41163-034-50	150 in 1 BAG; Type 0: Not a Combination Product	05/23/2017	



## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/23/2017	

**Labeler** - Supervalu Inc. (006961411)

**Registrant** - BestCo Inc. (002149136)

## Establishment

Name	Address	ID/FEI	Business Operations
BestCo Inc.		002149136	manufacture(41163-034)